

REMARKS

Applicant has amended claim 1 to more particularly point out and distinctly claim the subject matter which he regards as his invention. These amendments have necessitated the cancellation of claims 10 and 42 and the amendment to claim 11. Applicant has also incorporated into claims 43 and 44 all of the limitations recited in claims 12 and 27, respectively. Further, Applicant has canceled claims 2-5 and 12-41, which are drawn to non-elected embodiments. Finally, Applicant has canceled claims 6-9, which are identical to claims 6-9 of the parent U.S. Application 10/252,251. No new matter has been introduced by the above amendments.

Claims 1, 11, 43, and 44 are currently pending. Reconsideration of the application, as amended, is requested in view of the remarks below.

Double patenting objection

The Examiner objects to claims 42-44 as being substantial duplicates of claim 6. See the Office Action, page 2, lines 13-14. Specifically, the Examiner asserts that "it appears that *Magnolia biondii Pamp.* is the same herb as *Flos Magnoliae*. Therefore, there is no difference between claims 6 and 42-44." See the Office Action, page 3, lines 4-6.

Applicant has canceled claim 6 and requests that this objection be withdrawn. However, to complete the record, Applicant would like to point out that, contrary to the Examiner's assertion, claims 42-44 are not duplicates of claim 6.

Claim 6 is drawn to a composition containing an extract of *Magnolia biondii Pamp.* Claim 42 is drawn to a composition containing an extract of *Flos Magnoliae*. As pointed out in the response dated October 28, 2004, the term "*Flos Magnoliae*" is the English translation of "Xin-Yi" or "Xin-Yi Hua" recited at page 2, line 4 of the Specification. It refers to the family of *Magnolia* that includes *Magnolia biondii Pamp.*, *Magnolia denudata Desr.*, *Magnolia sprengeri*, and *Magnolia liliflora Desr.*, all of which are recited at page 3, lines 5-6 of the Specification. Also see Exhibits A and B attached to the above-mentioned response. In other words, *Magnolia biondii Pamp* is a member of *Flos Magnoliae* (i.e., the *Magnolia* family) and is not the same as *Flos Magnoliae*, as asserted by the Examiner. Thus, claim 42 is not a duplicate of claim 6.

Claims 43 and 44, drawn to methods of treating disorders, are also not duplicates of claim 6, drawn to a composition.

Rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph

Claims 1, 6-11, and 42-44 are rejected under § 112, 1<sup>st</sup> paragraph on two grounds. Applicant traverses each ground below.

I

The Examiner rejects claims 1, 6-11, and 42-44 as failing to comply with the enablement requirement. See the Office Action, page 3, lines 13-16. Applicant has canceled claims 6-10 and 42 and will only discuss claims 1, 11, 43, and 44.

Original claims 1 and 11 are directed to a nutraceutical composition containing extracts of four herbs, including an extract of an anti-allergy herb. Original claims 43 and 44 cover methods of treating disorders related to excessive secretion of histamine and interleukin-4 with a composition containing, among others, an extract of anti-allergy herb. Applicant has limited the anti-allergy herb recited in the original version of these four claims to *Flos Magnoliae*.

The Examiner asserts that “the Specification, while being enabling for a composition comprising ... *Magnolia liliiflora*, does not reasonably provide enablement for any anti-allergy herb.” See the Office Action, page 3, lines 14-16.

Given the limitation of the anti-allergy herb to *Flos Magnoliae*, Applicant submits that the Specification provides adequate enablement for *Flos Magnoliae*. As mentioned above, the term “*Flos Magnoliae*” refers to the family of *Magnolia*. The Specification already provides four members of the *Magnolia* family, i.e., *Magnolia biondii Pamp.*, *Magnolia denudata Desr.*, *Magnolia sprengeri*, and *Magnolia liliiflora Desr.* See page 3, lines 4-6. It indicates that each of these four members is an anti-allergy herb and a composition containing it is effective in treating allergy by inhibiting excessive secretion of histamine or interleukin-4. See page 3, lines 9-11. Further, the Specification cites two articles on *in vitro* assays for routine evaluation of this therapeutic efficacy.<sup>1</sup> See page 4, lines 25-28. It also describes a clinical study on treating allergy with two compositions, one of which contains an extract of *Magnolia biondii Pamp*, i.e.,

<sup>1</sup> The contents of these two articles are incorporated by reference into the Specification in their entirety. See the Specification, page 5, lines 22-23.

a member of *Flos Magnoliae*. See page 4, line 29 to page 5, line 16. In view of these teachings, one skilled in the art would know how to identify a member of *Flos Magnoliae* (from the Specification and the knowledge in the art) and how to use it to treat allergy (by *in vitro* and *in vivo* assays). In other words, amended claims 1, 11, 43, and 44 are adequately enabled by the Specification.

The Examiner further contends that “it is not clear that Applicant[] [was] in possession of every species of plant which has anti-allergy properties since the instant specification only teaches two species of plants which would be efficacious in the instant composition” (emphasis original).<sup>2</sup> See the Office Action, page 4, line 19 to page 5, line 2.

As Applicant has limited the anti-allergy herb recited in the original version of claims 1, 11, 43, and 44 to *Flos Magnoliae*, enablement of these four amended claims only requires that Applicant possesses every species of *Flos Magnoliae*, not every species of anti-allergy herbs. Of note, the term “*Flos Magnoliae*” is well known at the time this application was filed. Thus, one skilled in the art can readily discern which plant is a species of *Flos Magnoliae*. It is therefore submitted that Applicant is in possession of every species of *Flos Magnoliae*.

In view of the above remarks, Applicant submits that amended claims 1, 11, 43, and 44 are adequately enabled by the Specification.

## II

The Examiner also rejects claims 1, 6-11, and 42-44 as failing to comply with the written description requirement. Specifically, the Examiner points out that “[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” See the Office Action, page 3, line 18 to page 4, line 2.

As discussed above, Applicant has limited the anti-allergy herb recited in the original version of claims 1, 11, 43, and 44, the only pending claims, to *Flos Magnoliae*. As also discussed above, Applicant was in possession of every species of *Flos Magnoliae* at the time this

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<sup>2</sup> In view of the Examiner’s “in possession” language, it appears that she has improperly equated the enablement requirement with the written description requirement.

application was filed. It is submitted that the subject matter covered by claims 1, 11, 43, and 44 is adequately described in the Specification.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejects claims 1, 6, 8, and 10 as being anticipated by Yu et al., U.S. Patent 6,039,954 (“Yu”). See the Office Action, page 6, lines 8-10.

Claims 6, 8, and 10 have been canceled. Pending claim 1, as amended, covers a nutraceutical composition containing extracts of four herbs: (1) *Hedysarum polybotrys Hand.-Mazz.* or *Astragalus membranceus Bge.*, (2) *Atractylodes macrocephala kodiz*, (3) *Lebedouriella seseloides (hoffm.) Wolff*, and (4) *Flos Magnoliae*.

The Examiner correctly points out that “Yu disclose[s] a composition comprising Fang Feng, Bai Zhu, and Hou Po for treating gastrointestinal disorders (See Table 1 for example). It is noted that Fang Feng is *Lebedouriella seseloides*, Bai Zhu is *Atractylodes* and Hou Po is *Magnolia officinalis* (which is analogous to *Magnolia biondii* ...).” See the Office Action, page 6, lines 11-14. However, Yu does not disclose a composition containing *Hedysarum polybotrys Hand.-Mazz.* or *Astragalus membranceus Bge.* as required by claim 1. Thus, claim 1 is not anticipated by Yu.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejects claims 1, 6-11, and 42-44 as being unpatentable over Cheng (1998, Abstract) in view of Whitson-Fishman, U.S. Patent 5,162,037 (“Whitson-Fishman”). See the Office Action, page 7, lines 17-19.

Initially, Applicant would like to point out that it is not clear which Cheng article is relied on by the Examiner. It appears that she relied on a Cheng article listed in Form PTO-1449 submitted on April 29, 2004. However, this form lists two articles authored by Cheng and published in 1998. Since these two articles disclose similar subject matter, Applicant discusses both of them (collectively referred to as “Cheng”) for the purpose of traversing this rejection.

Among the rejected claims, only claims 1, 11, 43, and 44 are pending. As mentioned above, Applicant has limited the anti-allergy herb recited in the original version of these four claims to *Flos Magnoliae*.

As correctly pointed out by the Examiner, Cheng discloses that a composition containing extracts of Huang qi (i.e., *Astragalus membranceus*), Bai Zhu (i.e., *Atractylodes macrocephala kodiz*), and Fang Feng (i.e., *Ledebouriella seseloides*) is effective in treating allergic rhinitis. However, Cheng does not disclose or suggest a composition containing an extract of *Flos Magnoliae*, as required by claims 1, 11, 43, and 44. Whitson-Fishman does not cure the deficiency in Cheng.

The Examiner asserts that, according to Whitson-Fishman, "*Magnolia officinalis* (aka *Magnolia biondii pamp*, aka hou po, aka *Flos Magnoliae*) was beneficially used as an anti-allergy agent (see [Example 13], col. 14, for example)." See the Office Action, page 8, lines 4-6. The Examiner clearly erred. Whitson-Fishman discloses that *Magnolia officinalis* can be used for the treatment of intestinal parasites and bacterial infection. See Examples 2 and 11. It does not disclose or suggest that *Magnolia officinalis* can be used as an anti-allergy agent, as asserted by the Examiner. Example 13 of Whitson-Fishman, relied on by the Examiner, mentions treating airborne allergy with a composition containing extracts of 10 herbs, none of which is *Magnolia officinalis*. As Whitson-Fishman does not disclose or suggest using *Magnolia officinalis* (i.e., a member of *Flos Magnoliae*) as an anti-allergy herb, one skilled in the art would not have been motivated to combine it with Cheng to arrive at a composition containing an extract of *Flos Magnoliae*, as required by amended claims 1, 11, 43, and 44. Note that the Examiner also erred in equating *Magnolia officinalis* with *Flos Magnoliae*. As discussed above, *Magnolia officinalis* is a member of, and different from, *Flos Magnoliae*.

For the aforementioned reasons, claims 1, 11, 43, and 44 are not rendered obvious by Cheng in view of Whitson-Fishman.

### CONCLUSION

Applicant submits that the grounds for rejection asserted by the Examiner have been overcome, and that claims 1, 11, 43, and 44, as pending, define subject matter that is enabled, described, novel, and nonobvious.

On this basis, it is respectfully submitted that all of the pending claims are now in condition for allowance, an action of which is requested.

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Respectfully submitted,

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